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REMARKS

I. Amendments to the Specification

Paragraph three is revised to correct a typographical error.

Paragraph 16 is revised to track the language of claim 18 as amended herein.

II. Remarks Regarding Claims

Claims 1-23 will be pending in this case after entry of this amendment. Claims 12, 18, 20, and 21 are amended herein. New claim 23 is added. Claims 1-23 are patentable for the reasons discussed below.

i. Background

It is often important to be able to maintain (or possibly establish) aseptic or sterile conditions in polymeric tubing during connection of one piece of tubing to another. For example, there is often a need to connect polymeric tubing to deliver flowable food or medical products (e.g., those used for dialysis treatment). This has been done by cutting the tubing by melting it with a heated wafer or hot knife and then joining two ends together before they cool to melt seal the ends together. However, this type of method is unreliable because variations in the melting and cutting process, sometimes result in imperfect seals, leaks, or bacterial infiltrations. Even if the process works as designed, there is opportunity for contamination because the heated ends of the tubing sections are uncovered and exposed to the surrounding environment in the time between the cutting/melting and joining.

The applicants have solved the foregoing problem with their present invention. Briefly, two tubing sections to be joined are placed in opposed end-to-end relation so that the axially facing surfaces are free from exposure to the surrounding environment. After the ends of the tubing sections are placed together an electromagnetic beam (e.g., a laser beam) is used to weld the two tubing sections together. This way the axially facing surfaces of the tubing sections are not exposed to the environment after the heating of the ends of the tubing sections, thereby reducing the opportunity for contamination. Further, concerns about contamination of the tubing from before the placing of the ends of the tubing sections in opposed end-to-end relation are alleviated because the electromagnetic beam can sanitize (or sterilize) the ends of the tubing sections in the process of welding the tubing sections together.

In another aspect of the invention, applicants have developed a novel way to seal the ends of tubing sections that is suitable for preparing tubing sections for being joined as described above. There are many different types of tubing already in use, some of which may not absorb electromagnetic radiation efficiently (at least not at some wavelengths). In order to allow electromagnetic radiation to be used to seal sections of tubing without worrying about the ability of the tubing to absorb radiation, a portion of the tubing section to be sealed is collapsed (e.g., pinched closed) and placed in contact with an energy absorption member constructed for absorbing energy from a beam of electromagnetic energy. Then, the beam is directed onto the energy absorption member. Heat is transferred from the energy absorption member to the tubing section portion by contact therewith to melt and seal the end the tubing section portion.

This method allows tubing to be sealed even if the tubing is not an efficient absorber of the electromagnetic radiation available. The seal isolates the interior of the tubing from contamination in the surrounding environment. The seal can also be broken relatively easily after the tubing section is joined to another tubing section as described above to connect the tubing sections.

ii. Claims 1-17 and 23

Claims 1-17 are patentable because the prior art fails to show or suggest a method of connecting tubing sections comprising placing two tubing sections in opposed end-to-end relation so that the axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment followed by directing an electromagnetic beam generally toward the ends of the tube sections to weld them together.

Claim 1 is directed to a method of connecting together two sections of tubing, comprising the steps of:

> "placing the two tubing sections in opposed, end-to-end relation so that axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment; and then
>
> directing an electromagnetic beam generally toward the location where the axially facing surfaces are in opposed, end-to-end relation for welding the two sections of tubing together at the location." (emphasis added)

As indicated by the phrase "and then", claim 1 recites that the steps are carried out in a particular order. First, the tube

sections are placed in end-to-end relation so that the axially facing surfaces (e.g., the insides of the tubes) are free from exposure to the environment. Then, a beam of electromagnetic radiation is directed to the location where the ends of the tubes are located to weld the tubes together. In the process of welding the ends of the tubes, the beam kills microbes at the ends of the tubes, thereby allowing the connection to be made aseptic or sterile if need be.

In contrast, U.S. Patent App. Pub. No. 2003143352 (Yang et al.) teaches a method of connecting tubing in which the ends of tubes are first heated by a laser. After the ends are heated to a temperature high enough for fusion, the laser is shut off and then the tubes are brought together to form a weld. See ¶¶ 70-71. One important difference between the Yang method and method of claim 1 is that in the Yang method the axially facing surfaces at the ends of the tubes are exposed to the environment between the time the laser is shut off and the time the ends of the tubes are brought together to form the weld. This creates the opportunity for contamination of the tubing. Yang, teaches that the laser may be re-energized after the welding is complete. See ¶ 71. However, this would require the laser to be operated twice, making the method less efficient than the method recited in claim 1. Moreover, there is no disclosure or suggestion of a method where welding of the tubes occurs only after they are placed in end-to-end relation.

Accordingly, claim 1 is submitted as patentable in that the prior art of record, including Yang, fails to teach or suggest a method of connecting tubing comprising the steps of first placing the ends of the tubs in end-to-end relation so that the axially facing surfaces are substantially free from exposure to the

environment followed by directing a beam of electromagnetic radiation to the location at which the ends of the tubes are located to weld the tube sections together. Claims 2-17, and 23 depend from claim 1 and submitted as patentable for the same reasons.

Claim 2 is also patentable for the additional reason that it specifies that the temperature of the tubing sections is below the melting temperature of the material forming the tubing during the placing of the two tubing sections in opposed end-to-end relation so that axially facing surfaces of the tubing sections are substantially free from exposure to the environment. In contrast, the tubing sections are above the melting temperature when they are brought together in the method of Yang et al., having already been heated above the melting temperature by the laser while their axially facing surfaces were exposed. Thus, claim 2 is patentable for the additional reason that Yang et al., and the other prior art of record fail to show or suggest placing the ends of two tubing sections in opposed end-to-end relation so that their axially facing surfaces are substantially free from exposure to the environment while they at sub-melting point temperatures and then directing an electromagnetic beam at the ends to weld the tubing sections together.

Claim 8 is also patentable for the additional reason that it specifies that the placing of the tubing sections in end-to-end relation includes bringing the axially facing surfaces of the tubing sections into engagement with each other. Again, in the context of claim 8, this means that the axially facing surfaces of the tubing sections are already positioned in engagement with each other when the electromagnetic beam begins heating the ends. In Yang et al., the axially facing surfaces of the tubing are

brought into engagement with each other after the ends are heated with electromagnetic radiation. Accordingly, claim 8 is patentable for the additional reason that the prior art of record fails to show or suggest placing the axially facing surfaces into engagement with each other in combination with the steps of claim 1.

New claim 23 depends from claim 13 and further specifies that the material provided for absorbing energy is a film capable of absorbing the energy. In this respect, claim 23 is similar to claim 4. New claim 23 is submitted as patentable for the same reasons as claim 1.

iii. Claims 18-22

As amended, claims 18-22 are directed to a method of sealing a tubing section portion by:

> "collapsing at least a portion of the tubing section;
>
> placing the collapsed portion of the tubing section in contact with an energy absorption member;
>
> directing a beam of electromagnetic energy onto the energy absorption member, the energy absorption member being constructed for absorbing energy from the beam; and
>
> transferring heat from the energy absorption member to the collapsed tubing section portion by contact therewith to melt and seal the collapsed tubing section portion in its collapsed configuration." (Emphasis added).

Claims 18-22 are patentable because the prior art of record fails to show or suggest a method of sealing a collapsed tubing section by placing the tubing in contact with an energy absorption member

and directing a beam of electromagnetic radiation onto the energy absorption member to melt and seal the tubing in its collapsed configuration.

Yang et al. do not address sealing a collapsed tubing section using an energy absorption member to absorb energy from an electromagnetic beam. The end cap 610 shown in Fig. 12 of Yang et al. and described in paragraph 132 is not used to seal a collapsed tubing section. The purpose of the end cap 610 is to block the open end of the tubing section. Yang et al. teach that a tubing section can be sealed by pinching the tubing between a hammer and anvil and directing a beam of electromagnetic radiation onto the tubing to fuse the pinched part of the tubing. Paragraphs 77-83. Yang, et al. assume that the tubing will absorb enough energy from the electromagnetic beam to be heated sufficiently without substantial conductive heating from the hammer or anvil (neither of which are descried as energy absorbing members). Paragraph 83.

Flanagan also fails to show or suggest the method of claim 18. Flanagan is directed to a method of bonding a polymeric material to a catheter tube using an electromagnetic beam (e.g., laser) to heat the materials to melt them and produce fusion. Rather than an energy absorption member, Flanagan teaches that the melting is achieved by suitably focusing the electromagnetic radiation and/or using a wavelength selected to be strongly absorbed by one or both of the materials.

Accordingly, claim 18 is submitted as patentable because the prior art of record fail to show or suggest sealing a section of tubing by collapsing the tubing, placing the collapsed tubing in contact with an energy absorption member and directing electromagnetic radiation onto the absorption member to melt and

seal the collapsed tubing. Claims 19-22 depend from claim 18 and are submitted as patentable for the same reasons.

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Conclusions

Applicants respectfully request consideration and allowance of claims 1-23 for the reasons discussed above. Applicants also respectfully request a copy of the IDS form submitted June 16, 2004 initialed by the Examiner to indicate the references cited therein have been considered.

The Commissioner is hereby authorized to charge $50.00 for access claim fee to Deposit Account No. 19-1345. The Commissioner is also hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,

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